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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/206,249	12/07/1998	MIRI SEIBERG	JBP438	5255

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EXAMINER	
MELLER, MICHAEL V	
ART UNIT	PAPER NUMBER
1655	
MAIL DATE	DELIVERY MODE
05/09/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/206,249	SEIBERG ET AL.	
	Examiner	Art Unit	
	MICHAEL MELLER	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 75-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support for the amendment to claim 75 of "wherein said phagocytosis is decreased such that not more than about 76 % of particulate material is ingested". There is nothing in the instant specification or original claims to support such language. Applicant is requested to put amounts into the claims that are actually supported by the instant specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 75-84 are rejected under 35 U.S.C. 102 (b) as being anticipated by JP 408143442 (see the entire translation supplied by applicant especially the claims, paragraph 8, abstract) and as evidenced by Van der Ven and Kwok.

JP 408143442 (Matsuura) teaches a water extract of soybeans used to treat eczema. Whole soybeans are ground and water is added and then the extract is filtered. The ground matter is heated but to a temperature which could read on 5 ^{0}C.

Both Kwok and Van der Ven teach that soymilk contains trypsin inhibitor activity (FF 14-19). Van der Ven obtains the soymilk using a process similar to that of Matsuura, in which soybeans are soaked in water, mashed, and the resulting liquid soymilk is filtered (see FF 7-8, 14). Kwok teaches that "most commercially available edible-grade soybean products actually retain 5-20% of the TIA present in the original raw soybean from which they were prepared (16). The extent of

destruction of TIA in soy milk for maximum nutritive value or protein efficiency ratio was reported to be 90%" (Kwok 4836, col. 2; FF 17).

Thus, the Board of appeals concluded, that the evidence supports the examiner's finding that Matsuura's soybean extract inherently contains trypsin inhibitory activity.

Applicant argues that the decision on Appeal from the Board of Appeals concluded that without additional testing, the soybean extract prepared in accordance with Matsuura would have inherently contained trypsin inhibitory activity. This is not true, what the Board concluded was that Kwok provides Figure 1 which shows that at 120°C, 90% inactivation of trypsin inhibitor activity occurs after more than 400 seconds, or more than 6 ½ minutes (FF 18-19). Thus, based upon the teachings of Kwok and Van der Ven, the 120°C heat treatment for 3 minutes of Matsuura would not have reasonably been expected to reach 90% inactivation, leaving more than 10% of the original soybean trypsin inhibitor activity as present in the finished ointment, which was used by Matsuura to treat a patient with eczema (FF 13). The evidence supports the Examiner's finding that Matsuura's soybean extract inherently contains trypsin inhibitory activity. This is what the Board stated not what applicant stated.

Applicants note that the Kwok and the Van der Ven references were both published after applicants date, but these references are used as evidentiary references, as noted by the Board in the decision on the bottom of page 9, the references are used to show anticipation by inherency and does not have to have a date before applicant's filing date.

Applicant argues that the Hu declaration filed 7/6/2010 teaches on page 32, paragraph 4 that the margin of error ranges from 11-15 % and then concludes that the Hu declaration stated that because of the assay variability, results of this assay that are at or below 18-20 % are considered as below the margins of detection of the reliable threshold to describe real biological activity. Applicant then points the examiner to table 3 of the Hu declaration. In table 3 it is stated that STI at 0.05 has 84 % inhibition.

Applicant argues that trypsin inhibition activity was tested for Examples A-K set forth in the Hu Declaration in comparison with soy trypsin inhibitor ("STI") samples and a soy preparation prepared in accordance with the above-captioned patent application [Hu Declaration, ¶4]. It was determined that while the 0.05% STI sample and the soy sample prepared in accordance with the above-captioned patent application had fairly significant % inhibition rates (respectively, 84% and 57.9%), Examples A-J performed in accordance with the teachings of the Matsuura publication had negligible inhibition rates. In addition, the 0.005%

STI sample and Example K demonstrated trypsin inhibition rates at 15.6% and 15.2% respectively, which are within the margin of error and might represent little or no trypsin inhibitory activity. [Hu Declaration, ¶5]. Thus, applicant alleged, it is unclear whether any of the preparations of Matsuura have any trypsin inhibitory activity.

Fact is, table 3 shows both STI at 0.005% and sample K as having 15.6 and 15.2 % inhibition, respectively. Applicant alleges that these amounts are within the margin of error and might represent little or no trypsin inhibitory activity. While this is noted, it is not agreed with. Not only does sample K have 15.2 % inhibition of trypsin of sample, sample K also has 15.2 % trypsin activity of 1 % soy preparation as shown in table 3 of the Hu declaration. Thus, clearly there is some activity. Further, the alleged unexpected results are not commensurate in scope with the claimed invention. Further it is noted that sample K has STI inhibitory activity anywhere from 15.2-30 % (as noted by the declaration- which would read on 24 %) so clearly once again there is trypsin inhibitory activity in Matsuura and clearly the results in the declaration are inconclusive since three different assays yielded three different results as shown in table 1 of the Hu declaration.

Applicant argues in their response filed 3/1/2011 that allegedly Matsuura (hereafter JP) teaches only housewives eczema and that allegedly this is not the

same thing as eczema. While this is noted it is clearly without merit as eczema is clearly taught at paragraph 19 of the translation as being atopic eczema. Thus, the argument is without merit.

Applicant again argues that JP allegedly deactivates his proteins but once again JP clearly teaches temperatures of 5 ℃ which would not deactivate any proteins since this is not a hot temperature. Thus, JP does teach STI and the claimed invention.

Dr. Lin's declaration filed 3/1/2011 has been carefully considered but is not persuasive since JP does not read on soymilk since soymilk is denatured whereas JP as explained above is not.

Dr. Hu's declaration as already been commented on. Applicants contend that the +/- 15 % is not a real biological activity, but then what do the numbers mean ? With a statement such as that on the record the numbers are then meaningless. What Hu's declaration shows is that the numbers are meaningless. In fact, if one looks at Table 2 of the Hu declaration, untreated reads on 88 % ingested (since 100 +/- 12), at STI (0.01%) the % ingestion reads on 61 (since 76 +/- 15), thus the instant invention is no better than the untreated, in fact, it's worse for % ingestion !

Further, clearly a therapeutically effective amount of the composition was used in JP since the eczema was treated in JP.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 75-84 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over JP 408143442 (see the entire translation supplied by applicant especially the claims, paragraph 8, abstract) and as evidenced by Van der Ven and Kwok.

JP 408143442 (Matsuura) teaches a water extract of soybeans used to treat eczema. Whole soybeans are ground and water is added and then the extract is filtered. The ground matter is heated but to a temperature which could read on 5 ^{0}C.

Both Kwok and Van der Ven teach that soymilk contains trypsin inhibitor activity (FF 14-19). Van der Ven obtains the soymilk using a process similar to that of

> Matsuura, in which soybeans are soaked in water, mashed, and the resulting liquid soymilk is filtered (see FF 7-8, 14). Kwok teaches that "most commercially available edible-grade soybean products actually retain 5-20% of the TIA present in the original raw soybean from which they were prepared (16). The extent of destruction of TIA in soy milk for maximum nutritive value or protein efficiency ratio was reported to be 90%" (Kwok 4836, col. 2; FF 17).
>
> Thus, the Board of appeals concluded, that the evidence supports the examiner's finding that Matsuura's soybean extract inherently contains trypsin inhibitory activity.
>
> Further it is noted that sample K of JP has STI inhibitory activity anywhere from 15.2-30 % (as noted by the declaration-which would read on 24 %) so clearly once again there is trypsin inhibitory activity in Matsuura

Matsuura teaches a composition comprising an water extract of soybean as the active ingredient therein which appears to be identical to (and thus anticipate) the presently claimed composition since both were prepared from soybean using water. Consequently, the instantly claimed extract composition appears to be anticipated by the cited reference.

In the alternative, even if the claimed extract composition is not identical to the referenced extract composition with regard to some unidentified characteristics, the

differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced extract composition is likely to inherently possess the same characteristics of the claimed extract composition. Thus, the claimed extract composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Further, if not anticipated, the result-effective adjustment of particular conventional working conditions (e.g., grinding procedures, membranes used, defatting, temperature for soaking in water, etc.) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the ordinary artisan.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether the claimed extract differs and, if so, to what extent, from extract disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Please also note that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966

(Fed. Cir. 1985). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Applicants in their response filed 3/1/2011 argue that the differences are not slight, but as noted above the numbers are meaningless. Further, clearly a therapeutically effective amount of the composition was used in JP since the eczema was treated in JP.

Applicants argue that Kwok relates to a mathematical model developed in order to predict the optimal time-temperature combination to process soy foods, to achieve maximal bacterial destruction, maximal TIA inactivation and minimal deterioration in nutritional and sensory qualities. Accordingly, applicants argue, there would simply be no motivation to increase the percent of active trypsin inhibitory activity and the presently claimed invention is not obvious in view of JP but Kwok was used to cite that soymilk contains trypsin inhibitory activity not motivation, thus the argument is moot and unfounded.

Claims 75-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 408143442 (see the entire translation supplied by applicant especially the claims, paragraph 8, abstract) and as evidenced by Van der Ven and Kwok.

JP 408143442 teaches a water extract of soybeans used to treat eczema. Whole soybeans are ground and water is added and then the extract is filtered. The ground matter is heated but to a temperature which could read on 5 ^{0}C.

Both Kwok and Van der Ven teach that soymilk contains trypsin inhibitor activity (FF 14-19). Van der Ven obtains the soymilk using a process similar to that of Matsuura, in which soybeans are soaked in water, mashed, and the resulting liquid soymilk is filtered (see FF 7-8, 14). Kwok teaches that "most commercially available edible-grade soybean products actually retain 5-20% of the TIA present in the original raw soybean from which they were prepared (16). The extent of destruction of TIA in soy milk for maximum nutritive value or protein efficiency ratio was reported to be 90%" (Kwok 4836, col. 2; FF 17).

Thus, the Board of appeals concluded, that the evidence supports the examiner's finding that Matsuura's soybean extract inherently contains trypsin inhibitory activity.

Further it is noted that sample K has STI inhibitory activity anywhere from 15.2-30 % (as noted by the declaration which would read on 24 %) so clearly once again there is trypsin inhibitory activity in Matsuura.

In the event it is seen that the inhibitory activity claimed of at least about 24 % is not reached by Matsuura it is noted that in Matsuura and the declaration that sample K (which was used in Matsuura) had 15.2 % activity and the specification shows the results for the % of ingestion are always calculated plus or minus 11-15 (this is also true for % inhibition as shown on table 2 of the declaration) thus the results can come out unclear and since such is the case it is obvious to yield plus or minus 15 which will make the % of inhibition within the range claimed it is also obvious since to use amounts which yield plus or minus 15 % inhibition of trypsin inhibitory activity is well within the range of the ordinary artisan in an effort to optimize the desired results.

Where the general conditions of the claims are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Selecting a narrow range within somewhat broader range is obvious:

> Selecting a narrow range from within a somewhat broader range disclosed in a prior art reference is no less obvious than identifying a range that simply overlaps a disclosed range. In fact, when, as here, the claimed ranges are completely encompassed by the prior art, the conclusion is even more compelling than in cases of mere overlap. The normal desire

> of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.
>
> . . .
>
> We therefore conclude that a prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness. That is not to say that the claimed composition having a narrower range is unpatentable. Rather, the existence of overlapping or encompassing ranges shifts the burden to the applicant to show that his invention would not have been obvious, as we discuss below.
>
> *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003).

Applicant in their response filed 3/1/2011 argue that the amounts and numbers in Table 2 mean something, but as stated above they are meaningless.

JP teaches effective amounts used to treat eczema, thus it meets the claimed invention.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael V. Meller
Primary Examiner
Art Unit 1655

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